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09/513,086	02/24/2000	Linda S. Mansfield	MSU 4.1-458	4724

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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/513,086
Filing Date: February 24, 2000
Appellant(s): MANSFIELD ET AL.

Ian C. McLeod
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 29, 2006 appealing from the Office action mailed January 12, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

US application 09/670,355, filed February 20, 2000 is a related application sharing common inventors. In this application, similar subject matter directed to the nucleic acids that encode the protein antigens instantly claimed was appealed to the Board. The decision of the Board affirmed the rejections of record.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Hyun *et al.* Vet Parasitol. 2003 Feb 28;112(1-2):11-20.

Ellison *et al.* Int J Parasitol. 2002 Feb;32(2):217-25.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 4, 13 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

At issue are the amendments to the claims to recite "isolated", and "naturally occurring". Appellants do not point to support in the specification for the amendments to the claims and in a review of the present specification Examiner can not find support for the claim amendments. It was acknowledged that it appears that the specification would support *inter alia* "consisting" since it does contemplate the two proteins in a composition (for example page 5, lines 1-12).

However, the only support for "isolated" is in the context of a recombinant protein (page 9, lines 5-21). Further, there is no literal support for isolating the 16 and 30 kDa proteins directly from *Sarcocystis neurona* as a contemplated part of the invention. To the contrary, a review of the summary of the invention focuses on providing only recombinant proteins in the form of a fusion protein for isolation, as well as using DNA that can encode said fusion proteins, and provides no basis for the present invention to be an isolated protein from *Sarcocystis neurona*. In addition, there does not appear to be support for "naturally occurring" in the context of the claim. It has been acknowledged by the Examiner that while it would not be contested that such forms of the protein exist in nature, the literal support for this embodiment can not be found, in particular in the context of an "antigen" versus the protein itself that exists in nature. Importantly, it would imply non-naturally occurring forms of the protein/antigen, which is supported by the present specification at best in the context of a recombinant protein not in the embodiment that some sort of variants of the 16 and 30 kDa proteins were previously encompassed by the claims and taught by the present specification.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 4, 13 and 46 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Failure to provide the product claimed, and required by the claimed methods would require undue experimentation in initially just defining these proteins so that one could "isolate" the "naturally occurring" proteins, then would require fundamental and basic characterization of the isolated proteins to determine their sequence, and further research for the breadth of antigenic portions that could be predictably used in the methods as claimed.

Claims 4, 13, 46 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At issue is whether the specification meets the requirements of 35 USC 112, first paragraph, for the isolated forms of the naturally occurring proteins. The specification does not isolate the claimed proteins either singly or as a composition consisting of both proteins. The disclosure provides working examples, however no specific results and appear prophetic. It has been acknowledged that in the relevant art Western blots of all the proteins of *Sarcocystis neurona* have been separated on a two dimensional gel demonstrating multiple spots representing the forms of the proteins that are naturally occurring. However, neither the present specification nor the art of record at the time of filing has provided any specific information about the primary sequence of the protein antigens claimed. Moreover, a search of the relevant art for disclosure of the specific sequences instantly claimed indicate that this is still a subject of research, and that new isolates provide further evidence that variants of the specific sequence are present in nature

(see for example Hyun *et al.* Vet Parasitol. 2003 Feb 28;112(1-2):11-20, Sequence comparison of Sarcocystis neurona surface antigen from multiple isolates).

The basis of the rejection is most simply put by the example of where if a specific sequence is provided, whether the present disclosure provides sufficient description for the skilled artisan to recognize that the sequence was specifically contemplated as the invention. For example, Ellison *et al.* (Int J Parasitol. 2002 Feb;32(2):217-25. Molecular characterization of a major 29 kDa surface antigen of Sarcocystis neurona) teach a protein that meets the size requirements of the protein in the claimed composition, but given the present disclosure clearly the specific sequence of Ellison *et al.* would not have been predicted or even obvious given the present specification.

Case law has been cited to establish that one cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Appellants effective filing date. Importantly, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). In comparison of the fact pattern present in the case law and that presently claimed, it was noted that in *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. In that case the specification provided only the bovine sequence. In this case, no sequence information has been

provided, and at best the art at the time of filing and general guidance of the present specification provides a general means for isolating the 16(±4) kDa and 30(±4) kDa protein antigens

(10) Response to Argument

Claims 4, 13 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Appellants note that a claim need not be described literally in order for the disclosure to satisfy the written description requirement, citing MPEP 2163.02 is support (Appellants' brief page 9). Appellants acknowledge that the term "naturally occurring" is not found in the text, and provide a citation of Example 1 from the specification for the purification of antigens on two dimensional gels in order to produce monoclonal antibodies (Appellants' brief page 10). Appellants reiterate the second paragraph provided under 2163.02 (Appellants' brief pages 10-11), and argue that the example provides "purified proteins [that] are used as antigens for the production of antibodies" (Appellants' brief page11), and thus support for the instant claims.

Initially, it is noted that the means of isolating the protein in Example 1 cited by Appellants appear to be prophetic, and at best the guidance is of a general nature for techniques that potentially can be used. This is evidenced by the broad assertion that the antigens "were purified by methods known to the art for purifying antigens" and that the single specific example of two-dimensional gel electrophoresis is provided as one possible example as evidenced by the use of "i.e." in the same sentence. Similarly, the methods of using the isolated proteins also

appears to be prophetic in that the production of antibodies is given in alternative possible methodologies While working examples are not required, there is no evidence of record that the examples were actually practiced at the time of filing. All this is noted to address the issue to whether the specification clearly demonstrates possession at the time of filing. In this case, the evidence of record indicates that a composition consisting of "a single naturally occurring 16 (±4) kDA protein antigen isolated from *Sarcosystis neurona* and a single naturally occurring 30 (±4) kDA protein antigen isolated from *Sarcosystis neurona* in a pharmaceutically accepted carrier" (claim 1 and requirement to practice the methods of claims 13, 46 and 50) were not reduced to practice to demonstrate a physical possession of the claimed invention.

Examiner acknowledges that the subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. However, if a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. In this case, there is no evidence in example 1 of **how** the antigens were "*isolated*" as recited and required by the claims (the cited working example indicates that "the 16 (±4) kDA antigen and/or 30 (±4) kDA antigen were *purified*"). The terms purification or isolation by themselves do not provide a unique requirement that only one product results from any particular protocol. The prophetic example of using a two-dimensional gel provided indicates a means of separation, however there is no indication even here on how separated or isolated the proteins are, or how the are recovered from a gel or a blot to establish any level of purity or degree of isolation from other proteins

present in the sample. The analysis above applies to method known in the art for possible means to isolate an intact protein that can be detected. The breadth of the claim encompasses more than this in that it encompasses any antigen protein, not the entire protein as would be implied by working example. More specifically, an antigen is only a portion of a given protein, and does not require the entire intact protein. This was specifically discussed in the office action mailed July 11, 2005, bridging pages 2-3) stating that "the claims as amended recite "an" antigen, implying that there is more than one form the single naturally occurring protein. Again, consistent with the teachings of the instant specification the present claims can reasonably be interpreted to encompass fragments, and as related to their use in the method, fragments that have the functional property of being capable of treating *S. neurona* infection in equine." (office action bridging pages 2-3), which has not been contested by Appellants. Furthermore, it was noted that upon review of the specification the only literal support for "isolated" is in the context of a recombinant protein (page 9, lines 5-21).

Even if the cited working example were used to support some composition comprising isolated proteins, there is no literal support for isolating the 16 and 30 kDa proteins directly from *Sarcocystis neurona* as a contemplated part of the method claims, and to the contrary, a review of the summary of the invention focuses on providing only recombinant proteins in the form of a fusion protein for isolation, as well as using DNA that can encode said fusion proteins, and provides no basis for the present invention to be an isolated protein from *Sarcocystis neurona.* At best, the cited working example provides for isolating proteins to make antibodies.

The new matter rejection has been made because the claimed subject matter represents an addition and a departure from the subject matter specifically supported by the present

specification. At best, the working example relied upon by Appellants provides a basis for purifying proteins from *Sarcosystis neurona,* but fails to provide support for the claims as amended. As discussed above, the claims encompass more than simply naturally occurring proteins isolated from cultures of *S. neurona* by two dimensional electrophoresis, which the cited example fails to literally or figuratively support.

Claims 4, 13 and 46 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Appellants summarize the requirements of 35 USC 112, first paragraph, citing the Wands factors and *In re Colianni* (Appellants' amendment pages 12-14). Citing MPEP 2164.01(b) and *In re Fischer*, Appellants argue that the invention as claimed bears a reasonable correlation to the entire scope of the claims. Referring to example 1 Appellants assert that the proteins are isolated by two-dimensional gel electrophoresis and injected into mice to produce antibodies (Appellants' amendment page 14, also referring to page 33 of the specification).

Initially, it is noted that the injection into a mouse to generate monoclonal antibodies does not correlate with methods of "treating equine with a *Sarcicystis neurona* infection" (claim 13) or a more general method of treating any "disease caused by *Sarcicystis neurona* infection" (claim 46) as asserted by Appellants. Examiner would acknowledge that cited example supports the physical act of injection, however this fails to be correlative with any affect in the treatment of an infected horse. It was noted that in light of the failure of the specification to support the

claims as amended, one would conclude that a disclosure cannot teach one to make or use something that has not been adequately described. As provided in the art of record, a composition that comprises both the 16 and 30 kDa proteins of *Sarcicystis neurona* were known in the prior art (see Liang *et al.* ref U for example), and methods where horses were administered this composition comprising the 16 and 30 kDa proteins of *Sarcicystis* were practiced, however none of these suggest that they treat or prevent any aspect of *Sarcicystis* infection (see Fenger *et al.* IDS ref F1 for example) rather they were provided to cause the infection.

Claims 4, 13, 46 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Appellants summarize the requirements for determining compliance with the written description requirement, citing relevant case law (Appellants' brief pages 15-16). Appellants summarize the breadth of the claims as the "composition consists of naturally occurring protein antigens which are isolated from *Sarcicystis neurona* (Appellants' brief pages 16-17). It is argued that the claimed proteins are described by their physical properties of molecular weight, not by function, and are described also by their source by the requirement that they are isolated from *Sarcicystis neurona* (Appellants' brief page 17). It is argued that providing a starting material, the proteins motilities on a polyacrylamide gel and the ability to detect the proteins with available antisera is sufficient, and the amino acid sequence of the protein or the nucleotide sequence encoding them is not required (Appellants' brief page 17). Pointing the teachings in

Example 1, it is argued that one of skill in the art would be able to identify and isolate the 16 and 30 kDa antigens of *Sarcicystis neurona* (Appellants' brief page 18).

As noted in the final office action, Examiner acknowledges that Example 1 provides general methodology for two dimensional gel electrophoresis and even without this teaching one of skill in the art would be able to obtain both 16 and 30 kDa proteins form *Sarcicystis neurona* to some level of purity. Examiner agrees that methods of electrophoresis and immuno-assays are well known in the art, however this is insufficient to describe relevant structural and functional elements of the claimed product, nor does it provide any guidance to the antigens nor antigenic fragments would provide a form of treatment in the claimed methodology of treating equine. As indicated in the final office action "at issue is whether the specification even meets the requirements of 35 USC 112, first paragraph, for the isolated forms of the naturally occurring proteins" (see page 3 of the final office action mailed 7/11/2005). Again, a search of the relevant art for disclosure of the specific sequences instantly claimed indicate that this is still a subject of research, and that new isolates provide further evidence that variants of the specific sequence are present in nature (see for example Hyun *et al.* Vet Parasitol. 2003 Feb 28;112(1-2):11-20).

Most simply put would be an example where a specific sequence is disclosed and whether the present disclosure provides sufficient description for the skilled artisan to recognize that the sequence was specifically contemplated as the invention. For example, Ellison *et al.* (Int J Parasitol. 2002 Feb;32(2):217-25) teaches a protein that meets the size requirements of the protein in the claimed composition, but given the present disclosure clearly the specific sequence of Ellison *et al.* would not have been predicted or even obvious given the present specification.

Case law has established that one cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Importantly, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. In instant application no sequence information is provided.

In the decision of 09/670,355 (Appeal No. 2003-1919) the following analysis was provided regarding claims directed to the nucleic acid sequence and methods of use. It is being made of record because there is also an acknowledgement that neither the nucleic acid nor the amino acid sequence was know at the time of filing or by the present disclosure.

"With respect to the issue of conception in the context of an interference count, the Court of Appeals for the Federal Circuit, our reviewing court, has stated that "irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance requires a definition of that substance other than by its functional utility." Fiers v. Revel, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1604 (Fed. Cir. 1993). The court specifically rejected Fiers' argument "that the existence of a workable method for preparing a DNA establishes conception of that material." Id. In Enzo Biochem, Inc. v. Gen-

Probe Inc., 296 F.3d 1316, 63 USPQ2d 1602 (Fed. Cir. 2002), in determining whether or not a claim to a nucleotide sequence met the written description requirement, the court adopted a portion of the Guidelines proffered by the United States Patent and Trademark Office (USPTO). The court stated that:

> The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e__~., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of characteristics.

Enzo Biochem, 296 F.3d at 1324, 63 USPQ2d at 1613 (citations omitted).

In construing the above requirement, the court in In re Wallach, 378 F.3d 1330, 71 USPQ2d 1939 (Fed. Cir. 2004), recognized "that the written description requirement can in some cases be satisfied by functional description." Id., 378 F.3d at 1335. The court held, however, that

> such functional description can be sufficient only if there is also a structure-function relationship known to those of ordinary skill in the art. As we explained above, such a well-known relationship exists between a nucleic acid molecule's structure and its function in encoding a particular amino acid sequence: Given the amino acid sequence, one can determine the chemical structure of all nucleic acid molecules that can serve the function of encoding that sequence. Without that sequence, however, or with only a partial sequence, those structures cannot be determined and the written description requirement is consequently not met.

Id.

In the instant case, as noted by the rejection, neither the disclosure as filed, nor the prior art, discloses any sequence, either amino acid or nucleic, for either the 16(+4) kD and/or 30(+4) kD antigens. Consequently, the written description requirement is not met, and the rejection is affirmed." See Appeal No. 2003-1919, pages 4-5.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided by herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Joseph Woitach

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Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LINDA S. MANSFIELD, MARY G. ROSSANO, ALICE J. MURPHY and RUTH VRABLE

Appeal No. 2003-1919
Application No. 09/670,355

ON BRIEF

Before WILLIAM F. SMITH, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 10-12, 18-20, 44, 45 and 47-52. Claims 10 and 51 are representative of the subject matter on appeal, and read as follows:

> 10. A vaccine for protecting an equid from a Sarcocystis neurona infection comprising a DNA from Sarcocystis neurona that encodes at least a 16 ± 4 kDa antigen and/or 30 ± 4 kDa antigen of Sarcocystis neurona.

Co: 9.

51. A vaccine composition which comprises an effective immunizing amount of DNA derived from Sarcocystis neurona capable of inducing an antibody immune response, and a pharmacologically acceptable carrier.

Claims 10-12, 18-20, 44, 45 and 47-52 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, i.e., lack of adequate written description. In addition, claims 10-12, 18-20, 44-45 and 47-52 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, i.e., lack of enablement. Finally, claims 51 and 52 stand rejected under 35 U.S.C. § 112, second paragraph. After careful review of the record and consideration of the issues before us, we affirm the rejection of claims 10-12, 18-20, 44-45 and 47-52 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description, and the rejection of claims 51 and 52 under 35 U.S.C. § 112, second paragraph, and decline to reach the merits of the rejection of claims 10-12, 18-20, 44-45 and 47-52 under 35 U.S.C. § 112, first paragraph, for lack enablement.

DISCUSSION

1. Rejection under 35 U.S.C. § 112, first paragraph, written description

Claims 10-12, 1-20, 44, 45 and 47-52 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, i.e., lack of adequate written description.

According to the rejection, "[r]eview of the present specification, the art of record, and a search of the sequence databases for polynucleotides and/or polypeptide sequences of 16(±4) kD antigen and the 30(±4) kD antigen indicate that these sequences have not been identified nor described." Examiner's Answer, page 4. The rejection further contends "the limitation 'at least' in the claims does not limit the invention to 16(±4) kD and/or 30(±4) kD antigen of S. neurona and broadly reads on any antigen that is not disclosed. The specification describes general methods of cloning cDNA sequences from expression libraries; however, the sequences obtained by this method for 16(±4) kD and/or 30(±4) kD antigen are not disclosed." Id. at 4-5. The rejection concludes that "the claimed invention as a whole is not adequately described and is not conventional in the art as of Appellants' effective filing date." Id. at 5 (emphasis in original).

With respect to the issue of conception in the context of an interference count, the Court of Appeals for the Federal Circuit, our reviewing court, has stated that "irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance requires a definition of that substance other than by its functional utility." Fiers v. Revel, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1604 (Fed. Cir. 1993). The court specifically rejected Fiers' argument "that the existence of a workable method for preparing a DNA establishes conception of that material." Id.

In Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1602 (Fed. Cir. 2002), in determining whether or not a claim to a nucleotide sequence met the written description requirement, the court adopted a portion of the Guidelines proffered by the United States Patent and Trademark Office (USPTO). The court stated that:

> The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of characteristics.

Enzo Biochem, 296 F.3d at 1324, 63 USPQ2d at 1613 (citations omitted).

In construing the above requirement, the court in In re Wallach, 378 F.3d 1330, 71 USPQ2d 1939 (Fed. Cir. 2004), recognized "that the written description requirement can in some cases be satisfied by functional description." Id., 378

F.3d at 1335. The court held, however, that

> such functional description can be sufficient only if there is also a structure-function relationship known to those of ordinary skill in the art. As we explained above, such a well-known relationship exists between a nucleic acid molecule's structure and its function in encoding a particular amino acid sequence: Given the amino acid sequence, one can determine the chemical structure of all nucleic acid molecules that can serve the function of encoding that sequence. Without that sequence, however, or with only a partial sequence, those structures cannot be determined and the written description requirement is consequently not met.

Id.

In the instant case, as noted by the rejection, neither the disclosure as filed, nor the prior art, discloses any sequence, either amino acid or nucleic, for either the 16(±4) kD and/or 30(±4) kD antigens. Consequently, the written description requirement is not met, and the rejection is affirmed.

Appellants argue with respect to the rejection of claims 10-12, 18-20, 44, 45 and 47-50 that they had "possession of Sarcocystis neurona which contains DNA encoding the 16 ±4 and 30 ±4 antigens. Thus, the applicants have possession of Sarcocystis neurona DNA encoding the 16 ±4 and 30 ±4 antigens." Appeal Brief, page 7. Appellants argue further that "[c]onstructing and screening an expression library for clones containing DNA encoding a particular protein is routine in the art," and thus "a person of ordinary skill in the art following the applicants' disclosure would have a high expectation of success of recovering clones from an expression library that express the 16 ±4 or 30 ±4

antigens using the antibodies against the 16 ±4 and 30 ±4 antigens prepared as taught in Example 1." Id. at 8.

Appellants' arguments are not convincing. First, the fact that appellants had possession of Sarcocystis neurona is not sufficient to provide possession of DNA that encodes the 16 ±4 and 30 ±4 antigens. As noted above, even a partial amino acid sequence of the 16 ±4 and 30 ±4 antigens, which would necessarily require possession of the source of the DNA, i.e., possession of Sarcocystis neurona, would not be sufficient to provide written description support for the claimed DNA encoding the 16 ±4 and 30 ±4 antigens. In addition, as also discussed above, the existence of a workable method to obtain the DNA sequence is also not sufficient to demonstrate written description support.

With respect to claims 51 and 52, appellants argue that appellants have possession of Sarcocystis neurona DNA, which "would be expected to encode a plurality of antigens, including the 16 ±4 and 30 ±4 antigens. Therefore, when the DNA is inoculated into a horse, the antigens encoded thereon are expressed in the horse." Appeal Brief, page 10. According to appellants, "[c]laims 51 and 52 do not depend on knowing the DNA sequences encoding the plurality of antigens. The claims merely require that the DNA encode one or more Sarcocystis neurona antigens. Thus, the DNA can be the entire Sarcocystis neurona genome(intact or fragmented) or particular DNA fragments therefrom." Id. at 11.

The above argument is also not found to be convincing. The disclosure as filed does not provide written description support for the use of the entire Sarcocystis neurona genome (intact or fragmented) or particular DNA fragments therefrom as a DNA vaccine. The written description is limited to a "DNA vaccine that contains or expresses at least one epitope of an antigen that has an amino acid sequence substantially similar to a unique 16 (±4kDa) antigen and/or 30 (±4) kDa antigen of Sarcocystis neurona." Specification, page 1 (Field of the Invention); see also pages 5, 17, 24 and 26. Thus, the rejection of claims 51 and 52 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description, is affirmed for the reasons set forth supra with respect to the discussion of claims 10-12, 18-20, 44, 45 and 47-50.

2. Rejection under 35 U.S.C. § 112, second paragraph

Claims 51 and 52 stand rejected under 35 U.S.C. § 112, second paragraph, "as being vague and indefinite in the recitation of 'derived'. Is this DNA isolated from S. neurona?" Examiner's Answer, page 9.

This rejection is affirmed in view of appellants' statement that they will amend the term "derived" to "isolated." See Appeal Brief, page 20.

CONCLUSION

The rejection of claims 10-12, 1-20, 44, 45 and 47-52 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description, and the rejection of claims 51 and 52 under 35 U.S.C. § 112, second paragraph are affirmed. Because we affirm the rejection under 35 U.S.C. § 112, first paragraph, on the

basis of lack of adequate written description, we decline to reach the merits of the rejection under 35 U.S.C. § 112, first paragraph, for lack enablement.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith)
Administrative Patent Judge)
)
)
Eric Grimes) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Lora M. Green) INTERFERENCES
Administrative Patent Judge)

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